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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,413	02/08/2001	Bernard J. Banks	PC10901A	9774

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EXAMINER
HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
1614	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/779,413	Applicant(s) Bernard Banks, et al.
	Examiner Ray Henley	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *August 19, 2002 and December 10, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-11* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

CLAIMS 1-11 ARE PRESENTED FOR EXAMINATION

Applicants' Amendments filed August 19, 2002 and December 10, 2002 have been received and entered into the application. Accordingly, the specification and claims 1-11 have been amended, claims 12-14 have been canceled and Figure 1 has been added. In view thereof, the only remaining issue is presented below. The others issues raised in the Office action dated February 14, 2002 are withdrawn in light of Applicants' amendments.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al. (EP 0 882 719)[Harada et al. '719] and Harada et al. (WO 98/57938)[Harada et al. '938], each of record, for the reasons of record (reproduced below) as set forth in the Office action dated February 14, 2002, as applied to claims 10-14.

Harada et al. '719 and '938 teach the presently claimed compounds as endothelin receptor antagonist (see the abstract for each). Harada et al. '719 further teach pharmaceutical compositions containing such compounds and their use in the treatment of a variety of endothelin

mediated disorders, including those presently claimed, i.e., hypertension, congestive heart failure and chronic renal failure (page 5, lines 35-48 and page 18, Example 2).

The differences between the above and applicants' claimed subject matter lie in that the references fail to highlight:

(1) treatment of a companion animal; and

(2) a pack containing the active agent and an instruction means.

However, to the skilled artisan, applicants' claimed subject matter would have been obvious because:

(1) the references teach that the compounds are effective for treating endothelin mediated disorders and the selection of a specific host in which to practice such treatment would have been a matter well within the purview of the skilled artisan; and

(2) in the pharmaceutical/veterinary art, it is routine, if not required, to include a package insert containing instructions for the use of the packaged pharmaceutical. The specific printed information is not material covered under patent laws, but rather copyright laws. Also, even if such were covered under patent laws, the limitation in the claim relating to the instructions would be seen as a statement of intended use for the claimed composition which does not impart any physical limitation to the composition that is not found in, or made obvious by the prior art.

Applicants' arguments appearing at page 6, third paragraph - page 7 of the last filed amendment have been carefully considered, but fail to persuade the Examiner of error in his determination.

In particular, applicants have urged that because the prior art is silent with respect to a "longer duration of action". The Examiner first is uncertain as to what reference duration of action is being referred to as such is unclear.

Secondly, the Examiner has reviewed the present claims, but finds no limitation respecting the dosage rate or any other aspect that would reflect a "longer duration of action". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Finally, even if such a limitation were present in present claims 10-11, such would merely be taken to be a statement of intended use rather than a limitation that imparts a physical or otherwise material limitation to the claimed formulation that is not found in or suggested by the prior art.

Accordingly, for the above reasons, the claims are deemed to be properly rejected and none of the claims are allowed.

Applicants' amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.

RAYMOND HENLEY, III
PRIMARY EXAMINER
GROUP 1600

Henley; rjh
January 18, 2003